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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,225	01/16/2004	Wolfgang Albrecht	NI 160	2196

7590 02/12/2008

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EXAMINER	
HEITBRINK, JILL LYNNE	

ART UNIT	PAPER NUMBER
1791	

MAIL DATE	DELIVERY MODE
02/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,225	ALBRECHT ET AL.	
	Examiner	Art Unit	
	Jill L. Heitbrink	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Koros (US 5599380) with Brenner et al. (US 4973320) and Meyst el al. (US 4283289) cited to demonstrate an inherent state of fact.

3. As to claim 1, Koros (US 5599380) teaches a method of producing a polymeric membrane including: dissolving a first polymer(s) (preparing a first polymer) in a suitable solvent to form a core (blood compatible) solution (homogeneous solution) (col. 2, lines 56-61); dissolving a second polymer(s) (preparing a second polymer)in a suitable solvent to form a sheath (tissue compatible) solution (homogeneous solution) (col. 2, lines 62-63); coextruding the core (blood compatible) and sheath (tissue compatible) through a spinneret (contacting solutions) orifice (nozzle) to provide a multicomponent fiber membrane (layered polymer) (col. 2, lines 64-67); introducing the multicomponent fiber membrane into a coagulation bath to solidify the fiber (subject to phase inversion) (col. 3, lines 3-6); and extracting the solvent (non-membrane components freed) (col. 7, lines 1-4). Although Koros (US 5599380) does not expressly state the first and second polymers are blood compatible and tissue compatible, respectively, the references Meyst el al. (US 4283289) (col. 4, lines 28-30) and Brenner et al. (US 4973320) (col. 3, lines 9-12) specifically teach that the first and second

polymers used in Koros (US 5599380) are blood compatible and tissue compatible, respectively. As to claim 2, Koros (US 5599380) teaches an additional step in the process described above including drawing the multicomponent fiber membrane (layered polymer) through an air gap (col. 3, lines 1-2). As to claim 3, Koros (US 5599380) teaches multicomponent hollow fiber membrane extruded through a spinneret (spin extrusion nozzle) (col. 3, lines 5-6 and col. 2, lines 64-67). As to claim 4, Koros (US 5599380) teaches extruding the polymer solutions through a multiple channel spinneret while maintaining a gas pressure in the hollow fiber (core) (col. 5, lines 49-54). As to claim 5, Koros (US 5599380) discloses a bore fluid (lumen filler) to facilitate generation of the hollow fiber (col. 6, lines 33-44). As to claim 6, Koros (US 5599380) teaches using a polyurethane outer layer (tissue compatible polymer) (col. 3, line 48) and a polyamide inner layer (blood compatible polymer) (col. 3, line 58). It is noted that Brenner et al. (US 4973320) specifically teaches that polyurethanes are tissue compatible (Brenner et al. (US 4973320) (col. 3, lines 9-12) and Meyst el al. (US 4283289) specifically teaches that polyamides are blood compatible (Meyst el al. (US 4283289) (col. 4, lines 28-30). As to claim 7, Koros (US 5599380) teaches that a common solvent dimethyl formamide (DMF) can be used (col. 8, lines 5-13). As each and every element of the claimed invention is taught in the prior art as recited above, the claims are anticipated by Koros (US 5599380).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koros (US 5599380), as described above in claims 1-7 above.

6. The teachings of Koros are as described above for claims 1-7. As to claim 8, Koros (US 5599380) does not expressly teach a specific additional polymer being common to both first and second polymers, however, Koros (US 5599380) states that the polymers used for the gas separation layer (tissue compatible layer) can be blended, substituted, or copolymers (col. 3, lines 47-50) and that the substrate layer (blood compatible layer) can be blended, copolymerized and substituted (col. 4, lines 1-2) suggesting that the two polymer layers can each be blended with an additional common polymer, such as polyamid, which is common to both layers as a choice for use (col. 3, line 31 and col. 3, line 59). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to blend a common polymer with the gas separation layer (tissue compatible layer) and substrate layer (blood compatible layer), as taught by Koros (US 5599380), because the additional common polymer may increase layer compatibility. As to claims 9 and 11, Koros (US 5599380) does not expressly teach a mass content of blood-compatible and tissue compatible polymers and the additional polymer in the total polymer content. However, it is submitted that an optimum polymer mass content is desirable and can be optimized through routine experimentation (MPEP 2144.05 II A). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize

the polymer mass content percent through routine experimentation. As to claim 10, Koros (US 5599380) does not expressly teach a concentration of the first and second polymer solutions. However, it is submitted that an optimum polymer solution concentration is desirable and can be optimized through routine experimentation (MPEP 2144.05 II A). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the polymer solution concentrations and can be optimized through routine experimentation.

Response to Arguments

7. Applicant's arguments filed Dec. 7, 2007 have been fully considered but they are not persuasive.

8. Applicant argues that Koros does not consider the polymers compatibility with blood or tissue. However, Koros , col. 12, lines 29-38, states that the multicomponent membrane can be used in "bioseparations".

9. Applicant argues that Koros discloses a multitude of polymers at col. 3, line 25 to col. 4, line 2 does not suggest one polymer layer being blood compatible and the other polymer layer being tissue compatible. Applicant is presently claiming the method of manufacturing wherein these steps of manufacturing are not argued, only the capatiblities of polymer with blood and tissue used in the method are argued. Applicant on page 5, lines 14-15 states: "From the literature, it is known which polymers are blood-compatible or, respectively, tissue-compatible." The examiner contends that the polymers disclosed by Koros would inherently meet the limitation of "blood-compatible" and "tissue-compatible" as known by those skilled in the art and from literature.

"COMTEMPORARY BIOMATERIALS" explains that a wide variety of materials are considered blood or tissue compatible depending upon the type of tissue, the type of blood, and the time of contact with the tissue or blood, such as at the middle of page 13 and page 201.

10. As stated in the MPEP 2131.02:

A SPECIES WILL ANTICIPATE A CLAIM TO A GENUS

"A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. In re Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (Gosteli claimed a genus of 21 specific chemical species of bicyclic thia-aza compounds in Markush claims. The prior art reference applied against the claims disclosed two of the chemical species. The parties agreed that the prior art species would anticipate the claims unless applicant was entitled to his foreign priority date.).

A REFERENCE THAT CLEARLY NAMES THE CLAIMED SPECIES ANTICIPATES THE CLAIM NO MATTER HOW MANY OTHER SPECIES ARE NAMED

A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that "the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. § 102(a), in that publication."). Id. at 1718. See also In re Sivaramakrishnan, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982) (The claims were directed to polycarbonate containing cadmium laurate as an additive. The court upheld the Board's finding that a reference specifically naming cadmium laurate as an additive amongst a list of many suitable salts in polycarbonate resin anticipated the claims. The applicant had argued that cadmium laurate was only disclosed as representative of the salts and was expected to have the same properties as the other salts listed while, as shown in the application, cadmium laurate had unexpected properties. The court held that it did not matter that the salt was not disclosed as being preferred, the reference still anticipated the claims and because the claim was anticipated, the unexpected properties were immaterial.).

Additionally, Koros anticipates the claimed invention since some of the materials are specifically known to have the capatiblities claimed.

11. Applicant's argue that Koros is related to gas separation membranes which is not considered in context, or has anything to do, with blood or tissue contact. Examiner notes that the present claims are directed to the method of manufacturing a membrane. However, the blood-gas interface use with the transfer of oxygen or carbon dioxide is shown in "CONTEMPORARY BIOMATERIALS", bottom of page 8. And, Koros , col. 12, lines 29-38, states that the multicomponent membrane can be used in "bioseparations".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jill L. Heitbrink whose telephone number is (571) 272-1199. The examiner can normally be reached on Monday-Friday 9 am -2 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill L. Heitbrink/
Primary Examiner, Art Unit 1791

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